

## REMARKS

In accordance with the forgoing, claims 1, 18 and 26 are amended, and claims 9 and 22 are cancelled, without prejudice or disclaimer of the subject matter therein. No new matter has been added as a result of this amendment. The following remarks are respectfully submitted.

### I. Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because there is poor line quality in the drawings and the numbers and reference characters are not plain and legible. Applicant has provided herewith new formal drawings, to address the deficiencies in line quality and legibility of numbers and reference characters, as cited by the Examiner, and respectfully requests that the Examiner withdraw the objection to the drawings.

### II. Rejections under 35 USC §102

Claims 1, and 5-7 stand rejected under 35 U.S.C. 102(b) as being anticipated by King (4,282,886). Applicant traverses the rejection of claims 1 and 5-7, asserting that King does not disclose every element and limitation of these claims.

Independent claim 1 defines a medical lead including, *inter alia*, a glue segment comprising a tissue adhesive encapsulated within a biocompatible capsule, which is formulated to rupture, when the lead is urged against a treatment site, in order to liberate tissue adhesive. Although King discloses a medical lead 10 including a ring of adhesive 16 protected by a foil cover 16a, the foil cover 16a is not an encapsulating capsule, is not described as being biocompatible, and is not described as being formulated to rupture when the lead 10 is urged against a treatment site. Rather, the foil cover 16a is shown by King, in Figure 3, to merely cover a downward facing surface of the ring of adhesive 16, and is described as being peeled away in column 2, lines 53-54. With further

reference to column 2, lines 50-58, lead 10, which is an epicardial lead, is initially positioned on an exterior surface of a heart wall in order to take thresholds, and, once a position of acceptable threshold is found, the position is noted, the foil cover is *peeled away*, and the lead is *repositioned* at the position earlier noted, where a gentle pressure is *subsequently* applied to bond the lead in place. Thus, the foil cover 16a cannot be likened to the capsule defined by claim 1 of the present application.

In light of the argument presented above, Applicant respectfully requests that the Examiner withdraw the rejection of claim 1 and claims 5-7, dependent thereon.

### **III. Rejections under 35 USC §103**

Claims 1, 6, 10, 13, 18, 22-24, 27, 30 and 35 stand rejected under 35 USC § 103(a) as being unpatentable over Parry et al. (6,718,212) in view of King. Applicant has canceled claim 22, without prejudice or disclaimer of the subject matter therein, rendering the rejection of claim 22 moot. Applicant traverses the rejection of claims 1, 6, 10, 13, 18, 23, 24, 27, 30 and 35, based on the following arguments.

Neither Parry et al. nor King, alone or in combination, teach or suggest every element and limitation of claim 1 and claims 6, 10 and 13, dependent thereon. By the Examiner's admission, Parry et al. do not disclose a glue segment comprising a capsule of tissue adhesive, and, as supported by the argument presented above, Applicant asserts that King does not disclose a biocompatible capsule, which is formulated to rupture, when the lead is urged against a treatment site, in order to liberate tissue adhesive, such as is defined by claim 1 of the present application.

Neither Parry et al. nor King, alone or in combination, teach or suggest every element and limitation of claims 18 and claims 23, 24, 27, 30 and 35, dependent thereon. Independent claim 18 defines a system for affixing a medical lead to a tissue site, which includes, *inter alia*, a glue segment disposed

at a distal end of the lead and a guard disposed about a body of the medical lead, being proximal to and in proximity to the glue segment; the guard is further defined to project outward from the lead body and to prevent the glue segment from contacting a wall of a catheter lumen through which the lead is advanced. Although the foil 16a of King may serve as a guard for the ring of adhesive 16, the foil 16a cannot be likened to the guard as defined by claim 18 of the present application. Furthermore, neither of Parry et al. and King describe leads having glue segments that would pass through a catheter lumen.

In light of the arguments presented above, Applicant respectfully requests that the Examiner withdraw the rejection of claims 1, 6, 10, 13, 18, 23, 24, 27, 30 and 35.

Claim 3 stands rejected under 35 USC § 103(a) as being unpatentable over King in view of Hammerslag (5,383,899). Applicant traverses the rejection of claim 3, based on the arguments presented above with respect to King and claim 1, and respectfully requests that the Examiner withdraw the rejection of claim 3.

Claim 4 stands rejected under 35 USC § 103(a) as being unpatentable over King in view of Munch et al. (6,463,335). Applicant traverses the rejection of claim 4, based on the arguments presented above with respect to King and claim 1, and respectfully requests that the Examiner withdraw the rejection of claim 4.

Claim 9 stands rejected under 35 USC § 103(a) as being unpatentable over King in view of Theeuwes et al. (6,726,920). Applicant has cancelled claim 9, without prejudice or disclaimer of the subject matter therein, rendering the rejection of claim 9 moot.

Claims 11 and 28 stand rejected under 35 USC § 103(a) as being unpatentable over Parry et al. in view of King and further in view of Williams et al.

(6,516,230). Applicant traverses the rejection of claims 11 and 28, based on the arguments presented above with respect to Parry et al. and King and claims 1 and 18, and respectfully requests that the Examiner withdraw the rejection of claims 11 and 28.

Claims 12 and 29 stand rejected under 35 USC § 103(a) as being unpatentable over Parry et al. in view of Makower et al. (US 6,602,241). Applicant traverses the rejection of claims 12 and 29 asserting that the combination of Parry et al. and Makower et al. does not establish a case of *prima facie* obviousness. Although, in the passage referenced by the Examiner, Makower et al. state that “chemical glues, adhesives, or an ingrowth matrix ... may be disposed on the delivery catheter 12 or introduced through the delivery catheter 12”, Applicant can find no motivation for one to modify the lead of Parry et al. by adding a glue segment as described by the Examiner. Parry et al. disclose a lead 50 including a *centrally disposed* pace/sense electrode 56 *surrounded by* a circular mesh plate 52, which is impregnated or coated with a *light-activated* adhesive 59 that polymerizes when exposed to intense UV light and body fluids (column 9, lines 37 and lines 52-57). Parry et al. further disclose a sheath 60 formed with a sheath lumen 61 through which a body 51 of the lead 50 is inserted as shown in Figure 4 (column 10, lines 42-44). With further reference to Figure 4 and column 10, lines 45-68, the Examiner will understand that UV light beams 80 are emitted from light pipes 62, which extend within a wall 65 of sheath 60, to impinge on the light-activated adhesive disposed on mesh plate 52, *which surrounds the centrally disposed electrode 56*, causing the plate 52 to adhere to an epicardium. Since the invention disclosed by Parry et al. calls for a light-activated adhesive and light source positioned as such, there is no motivation to add a glue segment within the electrode 56.

In light of the argument presented above, Applicant respectfully requests that the Examiner withdraw the rejection of claims 12 and 29.

Claim 20 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Hammerslag (5,383,899). Applicant traverses the rejection of claim 20, based on the argument presented above with respect to Parry et al. and King and claim 18, and respectfully requests that the Examiner withdraw the rejection of claim 20.

Claim 21 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Munch et al. (6,463,335). Applicant traverses the rejection of claim 21, based on the argument presented above with respect to Parry et al. and King and claim 18, and respectfully requests that the Examiner withdraw the rejection of claim 21.

Claim 26 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Theeuwes et al. (6,726,920). Applicant traverses the rejection of claim 26, based on the argument presented above with respect to Parry et al. and King and claim 18, and respectfully requests that the Examiner withdraw the rejection of claim 26.

Claims 31 and 34 stand rejected under 35 USC § 103(a) as being unpatentable over Parry et al. in view of King and further in view of Sigg et al. (US 6,931,286). Applicant traverses the rejection of claims 31 and 34, based on the argument presented above with respect to Parry et al. and King and claim 18, and respectfully requests that the Examiner withdraw the rejection of claims 31 and 34.

Claim 32 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Starksen (5,571,161). Applicant traverses the rejection of claim 32, based on the argument presented above with respect to Parry et al. and King and claim 18, and respectfully requests that the Examiner withdraw the rejection of claim 32.

Claim 33 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Parry et al. in view of King and further in view of Igo et al. Applicant traverses the rejection of claim 33, based on the argument presented above with respect to Parry et al. and King and claim 18, and respectfully requests that the Examiner withdraw the rejection of claim 33.

**IV. Conclusion**

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters.

Respectfully submitted,

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Date

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